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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,419	03/19/2004	Jeffrey Conforti	CF-1	7252

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
10/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,419	CONFORTI, JEFFREY	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *16-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-23 are pending in the application, with claims 16-23 having been withdrawn from consideration, in response to the restriction requirement submitted on August 10, 2007. Accordingly, claims 1-15 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group I, namely claims 1-15, in the reply filed on September 10, 2007 is acknowledged. The traversal is on the ground(s) that the classes of search are identical for both groups and thus there is no search burden to the Examiner.

Applicants' arguments were not found persuasive. The arguments were not found persuasive because many products can be used with the process of Group I and thus the search for the products of Group II will not necessarily yield the process of Group I. Furthermore, if the product claims of Group II are found allowable, then the process claims of Group I will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai.*

Claims 16-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on September 10, 2007.

3. Applicants' election with traverse of: (1) desipramine as the species of an imipramine; and (2) fluphenazine as the species of a substituted phenothiazine, in the reply filed on September 10, 2007 is acknowledged. The traversal is on the ground(s) that the classes of search are identical for species and thus there is no search burden to the Examiner.

Applicants' arguments were not found persuasive. The Examiner maintains and argues that there is a search burden for imipramines because each imipramine is structurally distinct from one another. The Examiner further maintains and argues that there is a search burden for substituted phenothiazines because each substituted phenothiazine is structurally distinct from one another. Thus there would be a search burden for the Examiner to search for an imipramine and there would be a search burden for the Examine to search for a substituted phenothiazine.

Accordingly, claims 1-15 are examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement has not been submitted at the time of this Office Action.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means"

and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract has exceeded 150 words. The abstract has also exceeded the single paragraph limitation. Appropriate correction is required. See MPEP 37 CFR § 1.72 (b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (Journal of the American Medical Association, 1977, Vol. 238, No. 21, pp. 2291-2292), in view of Fluphenazine (Drug facts and comparisons, 1997, 1997, pp. 1605-1606), Jensen et al. (Drugs & Aging, 2001, Vol. 18, No. 10, pp. 737-749), and Desipramine (Drug facts and comparisons, 1997, page 1538).

Davis et al. teach 1 mg of fluphenazine, three times daily, alone or in combination with a tricyclic antidepressant (amitriptyline) is used to treat peripheral diabetic neuropathy (page 2291).

Davis et al. do not teach desipramine.

Fluphenazine teaches that fluphenazine is available as fluphenazine hydrochloride tablets at 1, 2.5, 5, and 10 mg tablets (pp. 1605-1606. Since fluphenazine hydrochloride is available in tablet form, it would be obvious that fluphenazine hydrochloride is taken orally. Fluphenazine fact information further teaches that the adult dose of fluphenazine hydrochloride is administered at 6 to 8 hour intervals (page 1605). Since fluphenazine hydrochloride is administered at 6 to 8 hour intervals, it would be obvious that in a 24-hour day, fluphenazine hydrochloride may administered two times a day at 8 hour intervals.

Jensen et al. teaches that tricyclic antidepressants, namely amitriptyline and desipramine, have been shown to be effective at treating diabetic neuropathy (abstract).

Desipramine teaches that desipramine is available as desipramine hydrochloride tablets at 10, 25, 50, 75, 100, and 150 mg tablets (page 1538). Since desipramine hydrochloride is available in tablet form, it would be obvious that desipramine hydrochloride is taken orally. Desipramine further teaches that the adult dose of desipramine hydrochloride may be administered in divided doses or as a single daily dose. Since desipramine hydrochloride may be administered in divided doses, it would be obvious that desipramine hydrochloride is administered divided into two daily dosages.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Davis et al. to be administered two times daily because the compounds of Flupenazine are compositions of fluphenazine hydrochloride administered at 8 hour intervals for twice a day administration and according to Fluphenazine, compositions comprising fluphenazine hydrochloride that is administered twice daily may be used for treating peripheral diabetic neuropathy.

The motivation to combine the compounds of Davis et al. to the compounds of Fluphenazine is that the compounds of Fluphenazine are compositions of fluphenazine hydrochloride administered at 8 hour intervals for twice a day administration and that such compositions can be used for treating peripheral diabetic neuropathy.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Jensen et al. to contain 10 mg of desipramine hydrochloride administered in two doses because the compounds of Desipramine are 10 mg of desipramine hydrochloride tablets administered in two doses and according to Desipramine, compositions comprising 10 mg of desipramine hydrochloride tablets administered in two doses may be used for treating diabetic neuropathy.

The motivation to combine the compounds of Jensen et al. to the compounds of Desipramine is that the compounds of Desipramineare compositions comprising 10 mg of desipramine hydrochloride tablets administered in two doses and that such compositions can be used for treating diabetic neuropathy.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Davis et al. and Fluphenazine to contain desipramine because the compounds of Jensen et al. and Desipramine are the tricyclic antidepressant desipramine and according to Jensen et al., compositions comprising tricyclic antidepressant desipramine may be used for treating diabetic neuropathy.

The motivation to combine the compounds of Davis et al. and Fluphenazine to the compounds of Jensen et al. and Desipramine is that the compounds of Jensen et al. and

Desipramine are compositions comprising the tricyclic antidepressant desipramine and that such compositions can be used for treating diabetic neuropathy.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding the amount of desipramine as 7 to 30 mgs/day and fluphenazine as 0.5 to 4 mgs/day as recited in instant claims 7 and 15, Desipramine disclose desipramine hydrochloride is available as 10, 25, 50, 75, 100, or 150 mg tablets (page 1538) and Fluphenazine disclose fluphenazine hydrochloride is available as 1, 2.5, 5, and 10 mg tablets (pp. 1605-1606), which closely meets the amount of desipramine and fluphenazine in a composition set forth in instant claims 7 and 15. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of desipramine and fluphenazine provided in a composition, according to the guidance set forth in Desipramine and Fluphenazine, to provide a composition having desired desipramine and fluphenazine content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

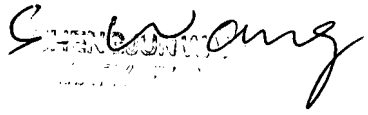
Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ckh